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| 10/071,779 | 02/07/2002 | Samuel Achilefu | MRD/ 75 | 4257 |

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| EXAMINER |
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JONES, DAMERON L

| ART UNIT | PAPER NUMBER |
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1616

DATE MAILED: 07/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/071,779

Applicant(s)

ACHILEFU ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-7, 10-14 and 20-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8, 15-17 and 19 is/are rejected.
- 7) ☒ Claim(s) 9 and 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 3.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1. 6) ☐ Other:

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APPLICANT'S INVENTION

1. Applicant's invention is directed to compositions and uses thereof having formula 4 as set forth in independent claims 1 and 8.

Note: Claims 1-22 are pending.

RESTRICTION INTO GROUPS

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-7, drawn to compositions of formula 4 as set forth in independent claim 1, classified in class 548, subclass 400+.
 - II. Claims 8-19, drawn to a method of performing a diagnostic procedure using the dye of independent claim 8, classified in class 424, subclass 9.6.
 - III. Claims 8-15 and 18-22, drawn to a method of performing a therapeutic procedure using the dye of independent claim 8, classified in class 514, subclass 359+.

Note: Claims appearing in more than one group will only be examined to the extent that they read on the elected invention.

3. The inventions are distinct, each from the other because of the following reasons: Inventions (I and II) and (I and III) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

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process of using that product (MPEP § 806.05(h)). In the instant case, the compositions may be used for either therapeutic or diagnostic purposes.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

ELECTION OF SPECIES

5. This application contains claims directed to the following patentably distinct species of the claimed invention: various species of claims 1-22 have multiple variables such as R20-R31, W1, W2, K1, K2, X1, X2, Y2, Z1, Z2, B1, C1, and D1 which depending upon the variable assignment generates species that are structurally different.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. During a telephone conversation with Ms. Beverly Lyman on 7/8/03 a provisional election was made with traverse to prosecute the invention of Group II, claims 8-19, and the species wherein W1 and W2 are CR10R11; Y2, Z1, and Z2 are (CH₂)_a-CONH-Bm; x1 and X2 are nitrogen; K1 and K2 are CH₂; R19 – R31 are hydrogen; R10 and R11 are C(CH₃)₂; A1 is a single bond; and A1, B1, C1, and D1 in combination form a six-membered carbocyclic ring. Affirmation of this election must be made by applicant in replying to this Office action.

Note: Initially, Applicant's elected species was searched. However, since no prior art was found which could be used to reject the elected species, the search was expanded to the species wherein K1 and K2 are CH; X1 and X2 are single bonds; Y2,

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Z1, and Z2 are hydrogen; W1 and W2 are CR10 R11 wherein R10 and R11 are hydrogen; A1 is a single bond; B1, C1, and D1 = CR10 R11 wherein R10 and R11 are hydrogen; a1 = 1; b1 = 1; and R19 – R23 and R24 – R31 are hydrogen. *It should be noted that the search was not further expanded because prior art was found which reads on the instant invention.*

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

WITHDRAWN CLAIMS

8. Claims 1-7, 10-14, and 20-22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

112 REJECTIONS

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 8, 15-17, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The claims as written are ambiguous because when X1 and X2 are single bonds, there is a valence problem (there are more than four bonds attached to the carbon atom).

103 REJECTIONS

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 8, 15-17, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turner et al (US Patent No. 6,329,531).

Turner et al disclose optical diagnostic agents for diagnosis of neurodegenerative diseases such as Alzheimer's disease. The in vivo diagnosis of such diseases may be performed using near infrared radiation (see entire document, especially, abstract; column 1, lines 6-20; columns 1-2, bridging paragraph; column 9, lines 3-40). The complexes of Turner et al have general formula I, $F(A_1)(B_n)(W_o)$ wherein F is a dye signal molecule which has at least one absorption maximum in the range of 600 – 1200 nanometers; A is a biomolecule that binds to beta amyloid plaques; B is a dye that binds to beta amyloid plaques; W is a hydrophilic, low molecular structural element that binds to beta amyloid plaques; m = 1 or 2, provide that n and o are zero or m = 3 – 20; l and n are independently 0, 1, or 2; and o = 0, 1, 2, 3, or 4, provided that the sum of l, n, and o

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are greater than or equal to 1 (column 2, lines 38-57). In particular, Turner et al disclose structures having formula (II) wherein R1 and R2 in combination form a six-membered aromatic ring; R7 and R8 in combination form a six-membered aromatic ring; R5 and R6 are E1 wherein E1 is hydrogen; $X = C(CH_2R_{13})(CH_2R_{14})$ wherein R13 and R14 are hydrogen; R3, R4, R9, and R10 are hydrogen; Q is the second structure appearing in column 4, line 41 of Turner et al; R11 is hydrogen; and $b = 3$ (column 3, lines 46-54; column 4, lines 16-65; column 5, lines 1-10). The biomolecule, A, may be antibodies, antibody fragments, peptides, proteins, receptors, enzymes, enzyme substrates, nucleotides, ribonucleic acids, deoxyribonucleic acids, lipoproteins, carbohydrates, monosaccharides, disaccharides, trisaccharides, linear or branched oligo- or polysaccharides, or saccharide derivatives (column 6, lines 20-26).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Turner et al and generate a species encompassed by Applicant's formula 4 used in a diagnosis method because Turner et al disclose a diagnostic method wherein a composition encompassed by Applicant's formula 4 is administered to a subject to diagnose neurodegenerative diseases such as Alzheimer's disease. Furthermore, a skilled practitioner in the art would recognize that when Applicant's variables are assigned the values K1 and K2 are CH; X1 and X2 are single bonds; Y2, Z1, and Z2 are hydrogen; W1 and W2 are $CR_{10}R_{11}$ wherein R10 and R11 are hydrogen; A1 is a single bond; B1, C1, and D1 = $CR_{10}R_{11}$ wherein R10 and R11 are hydrogen; $a_1 = 1$; $b_1 = 1$; and R19 – R23 and R24 – R31 are hydrogen, they read on the Turner et al when their variables are assigned the value R1 and R2 in

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combination form a six-membered aromatic ring; R7 and R8 in combination form a six-membered aromatic ring; R5 and R6 are E1 wherein E1 is hydrogen; X = C(CH₂R₁₃)(CH₂R₁₄) wherein R₁₃ and R₁₄ are hydrogen; R₃, R₄, R₉, and R₁₀ are hydrogen; Q is the second structure appearing in column 4, line 41 of Turner et al; R₁₁ is hydrogen; and b = 3.

CLAIM OBJECTIONS

13. Claims 9 and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Note: Claims 9 and 18 are allowable over the prior art of record for Applicant's elected species ONLY. The prior art neither anticipates nor renders obvious a method of performing a diagnostic procedure having the limitations of claims 9 and 18 in combination with those of their intervening claims.

COMMENTS/NOTES

14. The Examiner is aware of numerous applications filed by Applicant which contain similar subject matter. Thus, while the Examiner has searched pending applications and patented files for double patenting, some applications may have been inadvertently missed. Hence, the Examiner *respectfully requests* that applicant submit serial numbers of cases, not pending or newly filed, and copies of the pending claims which contain overlapping or related subject matter.


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15. It should be noted that the Turner et al reference cited above discloses the used of compositions encompassed within Applicant's formula 4 for diagnostic, not therapeutic, purposes.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri. (alternate Mon.), 6:45 a.m. - 4:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308 - 2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


D. L. Jones
Primary Examiner
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July 10, 2003